



RADx[®] Tech Fetal Monitoring Challenge



National Institutes of Health
Turning Discovery Into Health



National Institute of
Biomedical Imaging
and Bioengineering



Eunice Kennedy Shriver National Institute
of Child Health and Human Development

BILL & MELINDA
GATES *foundation*

Informational Webinar

October 5th, 2023

Today's Agenda

- **Opening Remarks**
- **Background**
- **RADx[®] Tech Fetal Monitoring Challenge**
 - Overview
 - Timeline
 - Eligibility
 - Submission Process & Requirements
 - Evaluation Criteria
- **Frequently Asked Questions**
- **Live Q&A Session**



Please type questions you have throughout the webinar in the Q&A box.



Questions submitted via the Q&A box will be answered at the end of the presentation.



Participants should remain muted.



The webinar will be recorded and made publicly available.

Today's Speakers



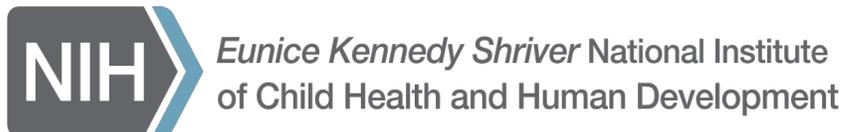
Bruce J. Tromberg, Ph.D.

Director, NIBIB



Monica Longo, M.D., Ph.D.

Chief Medical Officer
Pregnancy and Perinatology Branch
Division of Extramural Research, NICHD



C. Taylor Gilliland, Ph.D.

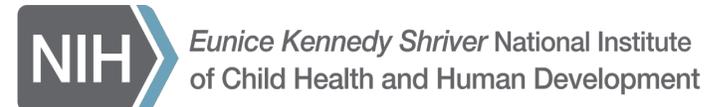
Senior Advisor for Innovation Programs
Office of the Director, NIBIB



NIBIB: *Technologies to Shape the Future of Health*

MISSION: Transform, through technology development, our understanding of disease and its prevention, detection, diagnosis, and treatment.

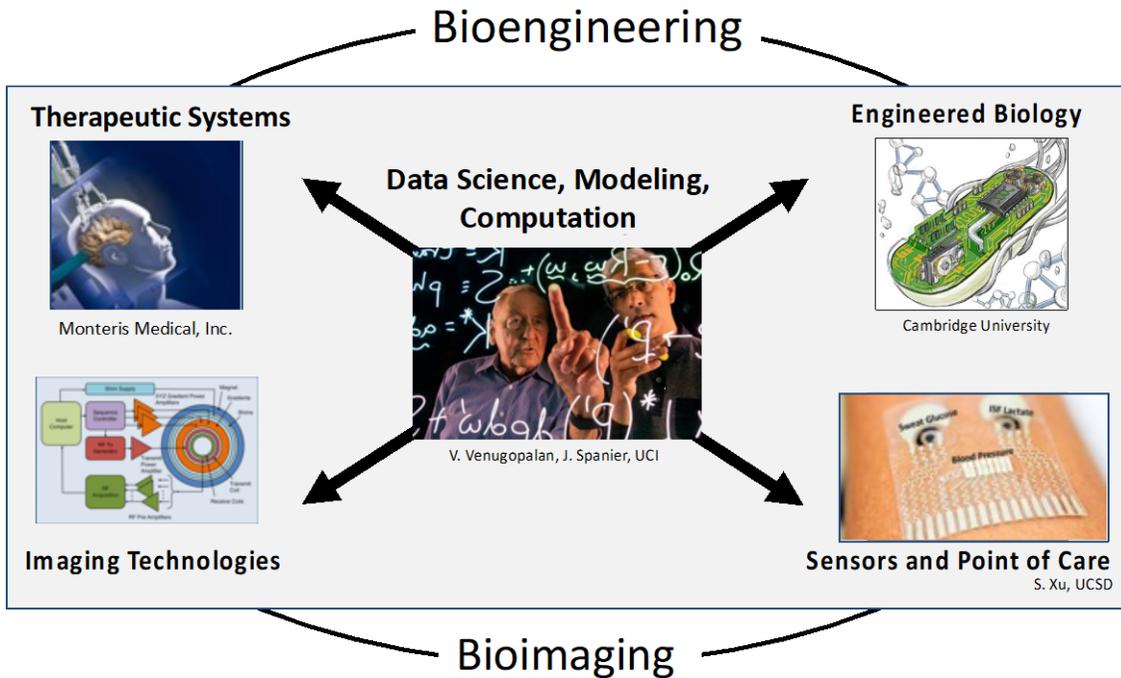
GOAL: Build purposeful, inclusive, interdisciplinary partnerships with public and private sector stakeholders to expand the impact of biomedical technologies.



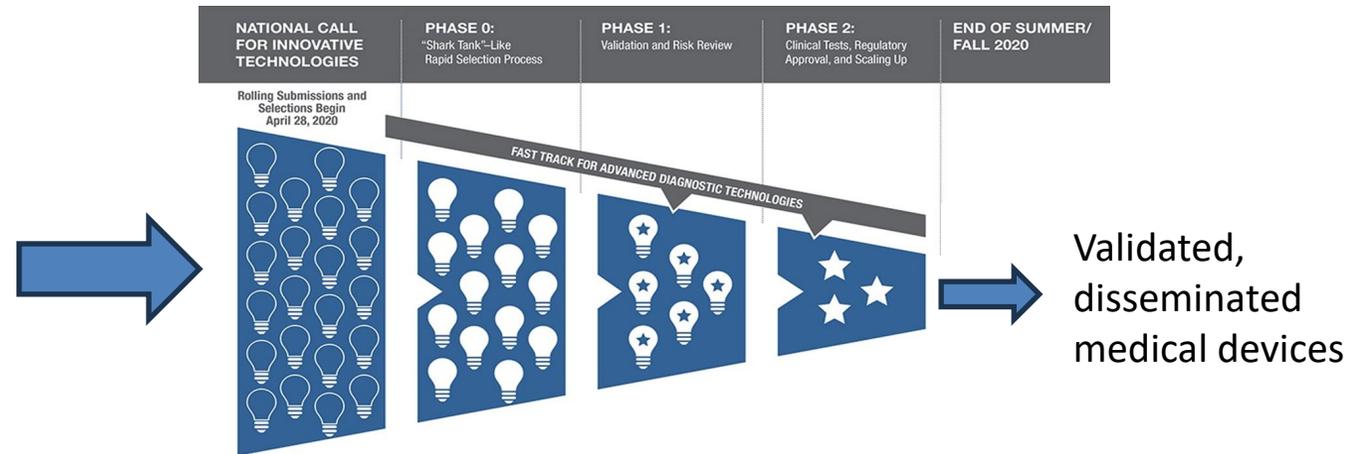
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NIBIB: Technologies to Shape the Future of Health

Emphasize 5 Major Tech Focus Areas



"RADx-ification" Innovation Funnel Process



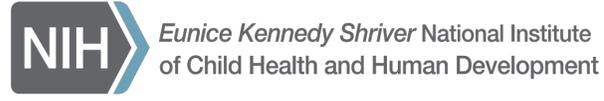
RADx Tech Fetal Monitoring Challenge Team

NIH Leads

C. Taylor Gilliland, NIBIB



Monica Longo, NICHD



Gates Foundation

- Amy Schellpfeffer
- Manu Vatish

NIH Working Group

- Afrouz Anderson, NIBIB
- Kari Ashmont, NIBIB
- Chris Cooper, NIBIB
- Tiffani Lash, NIBIB
- Ray MacDougall, NIBIB
- Shawn Mulvaney, NIBIB
- Antonello Pileggi, NICHD
- Linda Huynh, NICHD

RADx Coordination (CIMIT)

- Pam Miller
- Emily Kennedy
- Marshall Collins
- Michele Liston
- Tracy McMahon
- Santosh Savaliya
- Paul Tessier

History of Technologies to Monitor Fetal Health

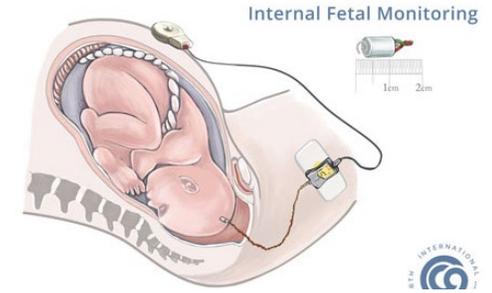
Early 20th century: Pinard stethoscope or fetoscope used for fetal heart rate monitoring.



1960s: The first fetal heart rate (FHR) monitor is introduced using doppler ultrasound to detect fetal heartbeat.



1980s: Invasive fetal scalp electrodes allowed for direct monitoring of the fetus's electrocardiogram.



1990s-present: Evolving of Doppler ultrasound and telemetry systems for wireless monitoring, providing more flexibility and freedom for the pregnant person during labor.



1970s: Continuous electronic fetal monitoring (EFM) was obtained by attaching sensors externally to the pregnant person's abdomen to monitor FHR and uterine contractions.



Throughout this evolution, fetal monitoring techniques have become more sophisticated, accurate, and accessible.

Limitations of Current Approaches

- **Continuous Monitoring**: uncomfortable for the mother because of the requirement to stay in a specific position for extended periods of time.
- **Invasiveness**: the use of invasive methods, such as fetal scalp electrodes or blood samples, carries a risk of infection and can only be performed in hospital setting.
- **Limited Data Analysis**: focused on FHR and uterine contractions, with limited insights into the **overall fetal health** (acidosis, hypoxia, etc.). Performs poorly in identifying fetuses with acute acidemia, due to a high false positive rate. Minimizes the potential for early detection of complications such as stillbirth.
- **Accessibility**: the need for healthcare professionals' expertise and specialized equipment to assess fetal monitoring limits access, particularly in rural or remote areas.

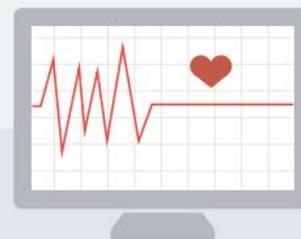
Goals for Fetal Health Status Monitoring

To identify fetuses at risk of stillbirth, perinatal fetal hypoxemia, and other conditions associated with fetal morbidity and mortality and to inform timely clinical intervention to prevent irreversible damage.

The Global Burden of Stillbirths

The burden of stillbirths is enormous, but overlooked.

Globally, **1** baby is stillborn every **16** seconds
nearly **4** every minute
over **200** every hour
nearly **5,400** every day
nearly **164,000** every month
nearly **2 million** a year



Over 40% of stillbirths occur after the onset of labour



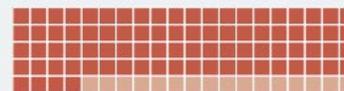
In the past two decades, **48 million babies** were stillborn



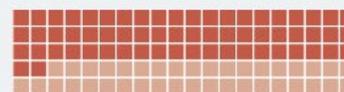
Three in four stillbirths occur in **sub-Saharan Africa or Southern Asia**



Low and lower-middle income countries account for **84% of all stillbirths**



but **only 62% of all live births**

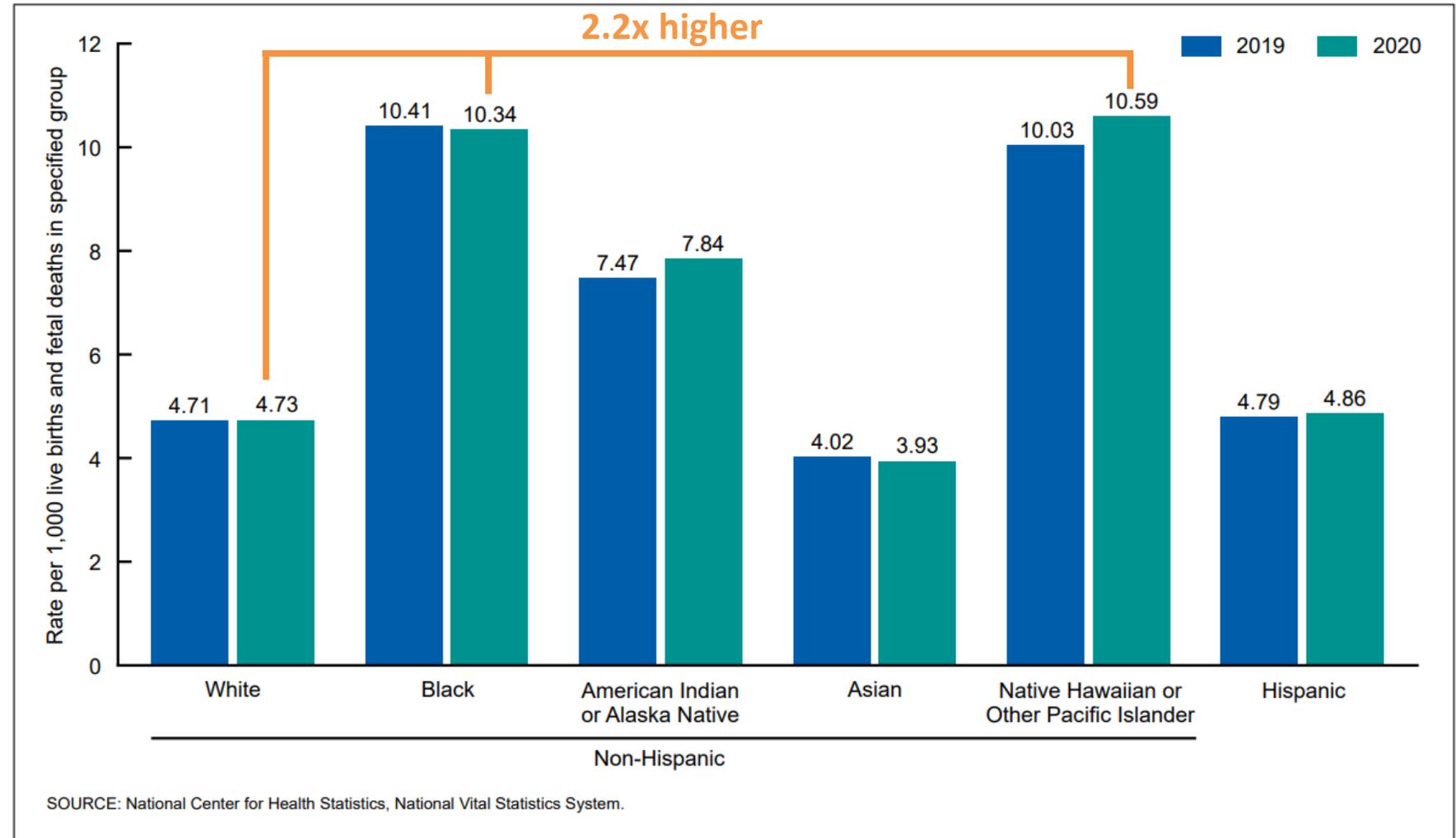


Most stillbirths are preventable with life-saving interventions and high-quality health care



Racial and Ethnic Disparities persist within the United States

Figure 2. Fetal mortality rates, by race and Hispanic origin of mother: United States, 2019 and 2020



20,854 fetal deaths* occurred in the U.S in 2020

U.S. fetal mortality rate = 5.74 fetal deaths per 1,000 live births and fetal deaths

Fetal mortality rates were highest for NHOPI (10.59), Black (10.34), and AIAN (7.84) women.

*defined as occurring at 20 weeks gestation or more

Opportunities for Innovation

- Thoroughly monitor fetal well-being to recognize and detect signs of fetal distress for timely and appropriate action to ensure the safety of the pregnant person and fetus.
- Prioritize non-invasiveness, mobility, advancements in data analysis, remote accessibility, and personalized care to improve fetal health outcomes while enhancing the experience for the pregnant persons.
- Continuous innovation and collaboration between medical professionals and technology experts is necessary to realize these future advancements.

RADx[®] Tech Fetal Monitoring Challenge



Problem

The unacceptable state of fetal health outcomes both within the U.S. and around the world calls for innovative and accessible technologies for determining fetal well-being across multiple physiological parameters during antepartum and intrapartum periods of pregnancy, especially in areas where there is limited access to high-quality prenatal healthcare.



Solution

Leverage NIH's Rapid Acceleration of Diagnostics Technology (RADx[®] Tech) "innovation funnel" to speed innovation in point-of-care and home-based diagnostic technologies that can help improve fetal and neonatal health outcomes through earlier and more accurate diagnosis, detection, monitoring of fetal health status and appropriate intervention.



Fetal Health Parameters *(examples)*

- Blood pH
- Blood oxygen saturation
- Placental perfusion
- Heart rate
- Inflammation



Technologies *(examples)*

- Wearable devices
- Smartphone/tablet-enabled diagnostic tools
- Integrated sensing and/or imaging technologies
- Digital health platforms
- *In vitro* diagnostics

Challenge Overview



Nation-wide Challenge awarding up to \$2 million in cash prizes for innovative and accessible technologies to enable earlier and more accurate diagnosis, detection, and monitoring of fetal health status in low-resource settings.

The Challenge focuses on improving fetal health outcomes during the late antepartum and intrapartum periods of pregnancy.

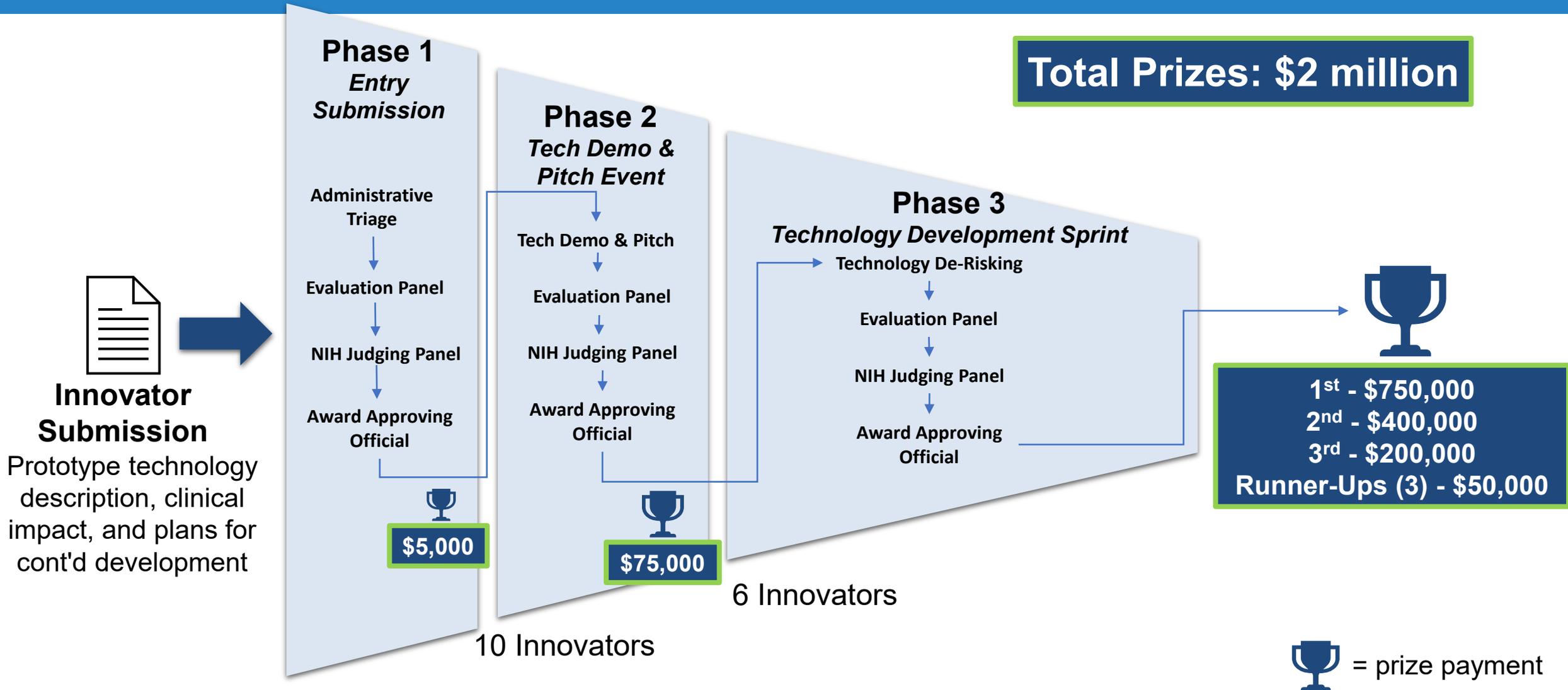
Innovators must submit a proposal describing in detail the diagnostic or monitoring technology, anticipated clinical impact, and plans for continued development.

Innovators must have a working prototype of a home-based or POC diagnostic technology that directly detects and measures one or more physiological parameters of the fetus itself.

Technologies must have strong potential for accessible, cost-effective use and impact in low-resource settings, such as low- and middle-income countries as well as areas of high-income countries where there is limited access to quality prenatal healthcare.

RADx Tech Innovation Funnel Challenge

Rapidly de-risk and validate technologies with stage-gated, milestone-based, cash prize awards



Challenge Timeline – Phase 1

**Challenge
Launched &
Submission
Portal Opened**



9/18

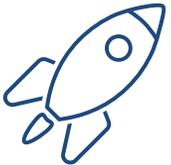
10/5

**Submission
Deadline**

11/17



12/15



**Informational
Webinar**



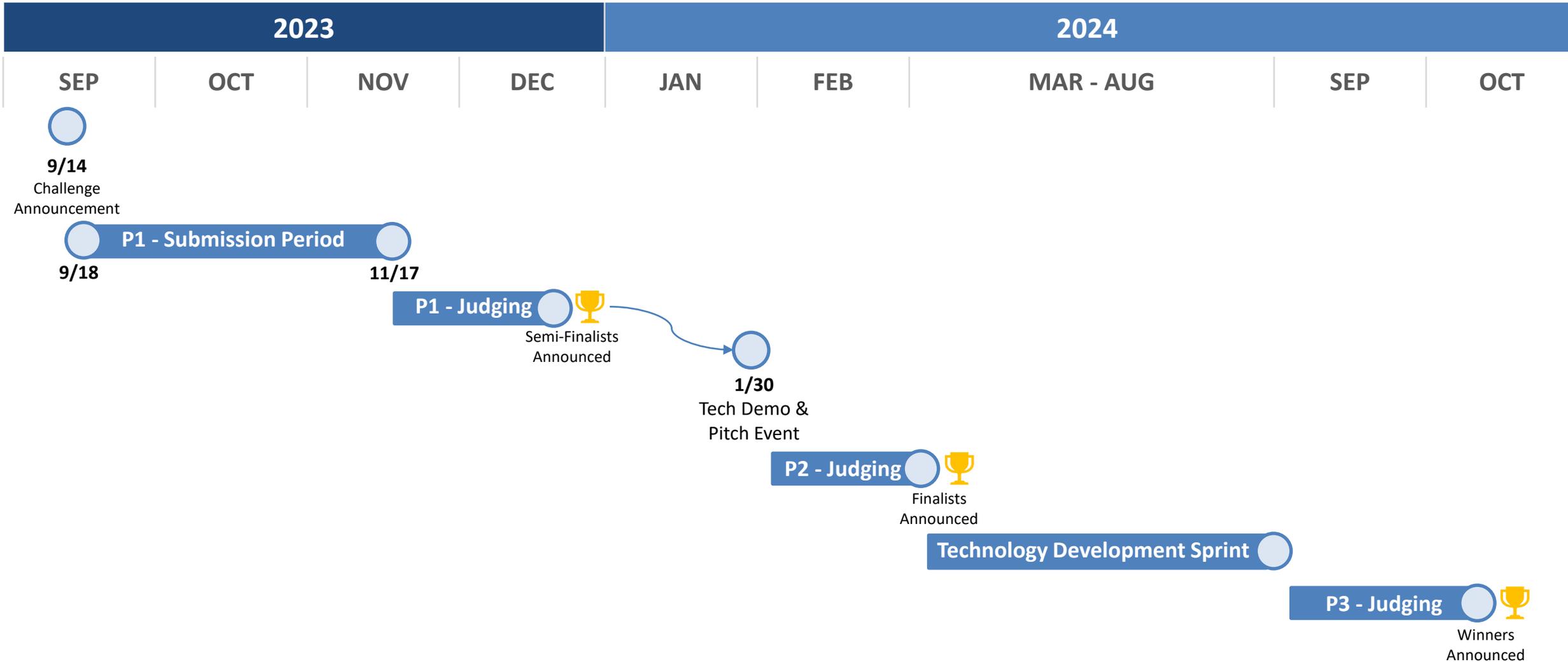
**Winners
Announced
(est.)**



**Technology
Demonstration
& Pitch Event***
January 30, 2024
Bethesda, MD

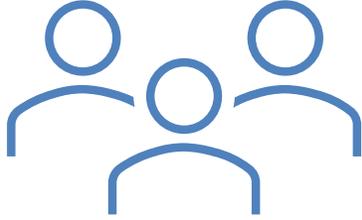
**only Phase 1 winners will be invited to the Phase 2:
Technology Demonstration & Pitch Event*

Challenge Timeline



Participant Eligibility

Carefully review the Eligibility and Participation Rules posted on [Challenge.gov](https://www.challenge.gov)



Team

Identify a **Team Captain** who will submit on behalf of a group of individuals.

If the Team wins, the **Team Captain** will be paid the cash prize in full.

The **Team Captain** must be a U.S. citizen or permanent resident to be eligible to receive a cash prize*.

**Non-U.S. citizens and non-permanent residents are not eligible to win a monetary prize (in whole or in part). Their participation as part of a winning team, if applicable, may be recognized when the results are announced.*



Entity

Identify a **Point of Contact** who will submit on behalf of a legally established organization, institution, or corporation.

If the Entity wins, the **Entity** will be paid the cash prize directly.

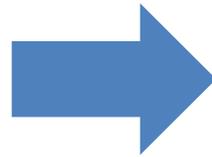
The **Entity** must be incorporated in and maintain a primary place of business in the United States to be eligible to receive a cash prize.

A Note About Using Federal Funds to Compete

An Innovator **may not use Federal funds** from a grant award or cooperative agreement to develop their Challenge submissions or to fund efforts in support of their Challenge submissions **unless use of such funds is consistent with the purpose, terms, and conditions** of the grant award or cooperative agreement.

IF

... you intend to use Federal funds, and
... the use of such funds is consistent with the purpose, terms and conditions of the award



THEN

... you must register for and participate in the Challenge as an **Entity** on behalf of the awardee institution or organization, and
... the prize must be treated as program income for purposes of the original grant or cooperative agreement in accordance with applicable Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR § 200)

Submission Process

1. All **Team** or **Entity** members must carefully review the complete Challenge Announcement posted on Challenge.gov.
2. The **Team Captain** or **Entity Point of Contact** must create an account in the Challenge submission portal. From the Challenge.gov post, click on "*Apply on external website*" and then navigate to "*How to Participate*" for instructions.



RADx® Tech Fetal Monitoring Challenge

Accelerating diagnostic innovation to improve fetal health outcomes.

Awarding \$2 million in prizes for innovative and accessible technologies to enable earlier and more accurate diagnosis, detection, and monitoring of fetal health status in low-resource settings.



Apply on external website

Follow challenge

Share

Submission period: Phase 1 opens on 09/18/23 06:00 AM PDT

Challenge type: Technology demonstration and hardware Scientific

Total cash prizes: \$2,000,000

[Print challenge](#)

Submission Requirements

- ✓ Project Title, Executive Summary, and description of Team/Entity
- ✓ Description of the technology, stage of development/maturity, and available analytical, clinical, or usability data on performance
- ✓ Description of the unmet clinical need being addressed, physiological parameter being measured, and intended use setting
- ✓ Plan for ensuring broad, accessible, cost-effective use and impact in low-resource settings
- ✓ Regulatory, intellectual property, manufacturing, and commercialization status and/or plans
- ✓ Anticipated deliverables during Phase 3 - Technology Development Sprint (if selected) and proposal for continued development to enable market entry

3. Provide all requested information and submit an entry in the portal no later than **11:59 PM Eastern Time on November 17, 2023.**

Technology Requirements



At a minimum, be a working prototype of a technology with data demonstrating the proof of concept.



Directly detect and measure one or more physiological parameters of the fetus itself. Physiological abnormalities of the umbilical cord or placenta will also be considered within scope.



Measure one or more parameters of fetal health status during the late antepartum and/or intrapartum periods of pregnancy.



Be either noninvasive or minimally invasive.



Be implementable at the point-of-care by a clinician or healthcare technician/provider in a hospital, clinic, or a community healthcare setting, or in an at-home setting by a caregiver or even ultimately the pregnant person themselves.



Have a reasonable likelihood of market entry within the next 5 years.



Have strong potential for accessible, cost-effective use and impact in low-resource settings, such as low- and middle-income countries as well as areas of high-income countries where there is limited access to quality prenatal healthcare.

Technology Evaluation Criteria



Scientific/ Technological

Scientific foundation and technical performance for diagnosis or monitoring



Clinical

Potential for improving fetal health outcomes by generating clinically-actionable information



Impact in Low- Resource Settings

Accessible and sustainable implementation and impact in low-resource settings



Commercialization & Regulatory

Strategy for achieving applicable regulatory approval and market entry in < 5 years



Innovation

Significant advancement over current approaches

Go to Challenge.gov for complete Evaluation Criteria

Frequently Asked Questions



How is the Challenge mechanism different from the NIH grant award process?

Challenges are a distinct mechanism from grants and are used to retrospectively award prizes to winners for the demonstrated and successful accomplishment of objectives set forth in the challenge. This Challenge will award cash prizes and provide in-kind support directly to teams or entities. There are no restrictions on how the prize award is to be used, except when federal funds are used to develop the challenge submission.

Our company is based outside of the United States. Are we eligible to compete in the Challenge?

No. For an Entity (*i.e.*, company, organization, institution, etc.) to be eligible to win a cash prize it must be incorporated in and maintain a primary place of business in the United States.



Can non-U.S. citizens or non-permanent residents participate in the challenge?

Yes, non-U.S. citizens and non-permanent U.S. residents may register for and participate in a challenge as members of a Team or Entity. However, non-U.S. citizens and non-permanent U.S. residents are not eligible to win a cash prize (in whole or in part). Such individuals may participate as part of a Team or Entity that otherwise satisfies the applicable eligibility criteria and may be recognized when the results are announced.

Frequently Asked Questions

Our technology infers or interprets fetal health status by measuring physiological parameters of the pregnant person. Is it within scope of the Challenge?



No. Technologies must directly detect and measure one or more physiological parameters of the fetus itself. However, technologies that detect and measure physiological abnormalities of the umbilical cord or placenta will also be considered within scope.

I have an idea or design for a diagnostic technology that addresses the requirements of the Challenge, but I don't have a working prototype yet. Would I be successful in this Challenge?



No. Technologies at the design or idea stage will not be considered responsive to this Challenge and are unlikely to be selected to advance. Innovators must have a working prototype with proof-of-concept data at a minimum.

Does my technology have to be completely new, or can we adapt or improve an existing technology?



The technology must represent either a scientific or technical approach that is novel, unique, and a significant advancement over the current standard of care or approaches or represent the innovative implementation of existing technology.

NIH POC Technology Conference & Showcase

Research and Innovation Translation Partnerships in Point of Care Technologies Conference and Technology Showcase



November 28-29, 2023

Natcher Conference Center
National Institutes of Health
Bethesda, MD

Register for free at:
tinyurl.com/poc-tech-conference

Live Q&A Session



Please type your questions in the Q&A box.



Participants should remain muted.



The webinar will be recorded and made publicly available.

If your question was not answered during the Q&A session:

1. Carefully review the complete Challenge details at www.challenge.gov/?challenge=radx-tech-fetal-monitoring
2. Check the FAQ page which will be updated regularly, www.pocotr.org/radx-tech-fetal-monitoring-faqs .
3. Send technical questions about the online submission form (CoLab) to CIMITwebmaster@partners.org .
4. Send content questions about the challenge to NIBIBchallenge@mail.nih.gov .